Comparison of two different methods of reducing pain during vaccination in infants: A clinical study

Dr. Gaurav Rajput

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Abstract
Background: Vaccination is a proven and one of the most cost-effective child survival interventions. The present study aimed at comparison of two different methods of reducing pain during vaccination in infants.

Materials & Methods: The present study was conducted on 120 infants visited to the department for vaccination. All were divided into 2 groups of 60 infants each. In group I, vaccination was done in constant milk feeding position. In group II, vaccination was performed following massage. Pain intensity was measured based on behavior scale.

Results: Group I, had 40 boys and 20 girls while group II had 25 boys and 35 girls. Mean pain score in group I was 3.2 and in group II was 4.5. The difference was non-significant (P< 0.05).

Conclusion: Both techniques found to be equally effective in controlling pain as there was no significant difference in pain intensity in infants.

Keywords: Infants, pain, vaccination

Introduction
Vaccination is a proven and one of the most cost-effective child survival interventions [1]. All countries in the world have an immunization programme to deliver selected vaccines to the targeted beneficiaries, specially focusing on pregnant women, infants and children, who are at a high risk of diseases preventable by vaccines. There are at least 27 causative agents against which vaccines are available and many more agents are targeted for development of vaccines. The number of antigens in the immunization programmes varies from country to country; however, there are a few selected antigens against diphtheria, pertussis, tetanus, poliomyelitis, measles, hepatitis B which are part of immunization programmes in most of the countries in the world [2].

Although pain transmission pathways have been thoroughly developed during infancy, pain inhibiting systems do not have adequate growth. On the other hand, limited cognitive abilities, lack of verbal and psychological skills, and constant changes occurring in infants are among the major challenges at this period of life. Therefore, evaluation and reduction of vaccination pain among infants are of great importance. As vaccination is essential for promotion of children's health, the infants have to experience pain in their very early life and inevitably face painful procedure of vaccination which causes them unpleasant mental and psychological effects [3]. The present study aimed at comparison of two different methods of reducing pain during vaccination in infants.

Materials & Methods
The present study was conducted in the department of Pediatrics. It comprised of 120 infants visited to the department for vaccination. All parent were informed regarding the study and written consent was obtained Ethical clearance was obtained prior to the commencement of the study.

General information related to patients such as name, age, gender etc. was recorded. In all infants, vaccination was conducted in hugging position. All were divided into 2 groups of 60 infants each. In group I, vaccination was done in constant milk feeding position. In group II, vaccination was performed with massage of the middle or ring finger of the infants' palm or sole of the injection side for 60 sec and finally vaccinated the subject.

Pain intensity was measured based on infants’ cry, respiration pattern and infants’ consciousness based on behavior scale. The lowest pain score is zero and the highest is 7, and score 3 shows the existence of pain.
Results were compiled and subjected to statistical analysis. P value less than 0.05 was considered significant.

Results

<table>
<thead>
<tr>
<th>Gender</th>
<th>Group I (Breast feeding)</th>
<th>Group II (Massage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boys</td>
<td>40</td>
<td>25</td>
</tr>
<tr>
<td>Girls</td>
<td>20</td>
<td>35</td>
</tr>
</tbody>
</table>

Table I shows that group I had 40 boys and 20 girls while group II had 25 boys and 35 girls.

Table 2: Comparison of pain in both groups

<table>
<thead>
<tr>
<th>Pain</th>
<th>Group I</th>
<th>Group II</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>3.2</td>
<td>4.5</td>
<td>0.12</td>
</tr>
<tr>
<td>SD</td>
<td>1.2</td>
<td>1.6</td>
<td></td>
</tr>
</tbody>
</table>

Table II, graph I shows mean pain score in both groups. Mean pain score in group I was 3.2 and in group II was 4.5. The difference was non-significant (P< 0.05).

Discussion

The benefits of immunization are not reaching to many children who are at the maximum risk of the diseases preventable by these vaccines. Majority of the children who do not receive these vaccines live in developing countries. As per the recent nation-wide survey data, of the targeted annual cohort of 26 million infants in India, only 61 per cent had received all due vaccines. Understandably, the implementation of vaccination programme and ensuring that the benefits of vaccines reach to each and every possible beneficiary is a challenging task [4].

Some effective non-medical methods to manage pain include cryotherapy, acupressure, distraction, and music therapy [5]. Medical methods are rarely used in infancy due to their side effects like skin rashes and irritations, while non-medical pain relief methods have not only numerous advantages including lack of side effects and interference with vaccination, but a pleasant effect on infants as well. Sujok is one of the non-medical treatment schools. “Su” in Korean means “palm” and “jok” means “sole.” This school of medicine has worked on various methods to activate adaptive palms/soles systems and their effect in the treatment of diseases and pain, based on a comprehensive system of physical and metaphysical mechanisms [6]. We included 120 infants in the study. They were divided into 2 groups. In group I, vaccination was done in constant milk feeding position. In group II, vaccination was performed following massage. We found that mean pain score in group I was 3.2 and in group II was 4.5. Abasi et al. [7] included a total of 99 infants in study. Three infants were left out due to restlessness and cry before injection. Data analysis was conducted for 96 subjects. Frequency distribution of subjects’ age (age group of 6 months and 12 months) and the type of injection (muscular or subcutaneous) in the massage therapy, breast feeding, and control groups were quite identical (each group 50%). Chi-square test showed no significant difference in the frequency distribution of sex in the three groups of massage therapy, breast feeding, and control. Frequency distribution of pain intensity showed the percentage of a painful condition in the massage therapy, breast feeding, and control groups as 63.6%, 43.8%, and 87.5%, respectively. Mean pain score in the breast feeding group was found to be significantly less than in the massage therapy and control groups. The highest vaccination mean pain score was for the control group.

The setting up of vaccine manufacturing units and grant of permission of clinical trials and final licensing and marketing authorization for vaccines in India is provided by the Central Drug Standards Control Organization (CDSCO), which is a National Regulatory Authority (NRA) in the country. The regulatory control over quality of drugs in the country is exercised through the Drug and Cosmetics Act, 1940. The schedule Y of this act regulates clinical and pre-clinical testing of the products. As per the Act, vaccines and other biological products are considered to be a ‘new drug’ and thus are governed by all rules and regulations applicable to a new drug [8].

Conclusion

Both techniques found to be equally effective in controlling pain as there was no significant difference in pain intensity in infants.

References